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APPLICATION NO.	LICATION NO. FILING DATE FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO. 8586	
09/763,666 05/25/2001		Stephen R. Ash	11020-55		
75	90 06/03/2003				
Gregory B Coy Woodard Emhardt Naughton Moriarty & McNett Suite 3700			EXAMINER		
			DAGOSTINO, SABRINA		
111 Monument	Circle				
Indianapolis, IN 46204			ART UNIT	PAPER NUMBER	
			3743	10	
			DATE MAILED: 06/03/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N	o.	Applicant(s)			
Office Action Summary		09/763,666		ASH, STEPHEN R.			
		Examiner	<del></del>	Art Unit			
		Sabrina Dago	stino	3743			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status	Decree of the second section (a) file does						
1)	Responsive to communication(s) filed on		final				
2a)☐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
•	on of Claims						
,—	4)⊠ Claim(s) <u>1-25</u> is/are pending in the application.						
4a) Of the above claim(s) <u>26-43</u> is/are withdrawn from consideration.							
· · · · · · · · · · · · · · · · · · ·	5) Claim(s) is/are allowed.						
· · · · ·	6)⊠ Claim(s) <u>1,2 and 6</u> is/are rejected.						
•	Claim(s) <u>3-5 and 7-25</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers  9) ☐ The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
• —	If approved, corrected drawings are required in re	ply to this Office	action.				
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	4) 5) 6)	Notice of Informa	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)			

Application/Control Number: 09/763,666

Art Unit: 3743

#### DETAILED ACTION

### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-25, drawn to a method for treating a patient, classified in class 604, subclass 28.
  - II. Claims 26-43, drawn to an infusion device, classified in class 604, subclass 503.
- 2. Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used with a materially different process. For example, it can be used to administer medication, without there being an infection or substantial risk of infection.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. During a telephone conversation with Mr. Coy on 5/22/03 a provisional election was made without traverse to prosecute the invention of a method for treating a patient, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Application/Control Number: 09/763,666 Page 3

Art Unit: 3743

## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sodemann (6166007).

Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device has been inserted in a patient comprising administering to the device a pharmaceutically effective amount of a composition comprising an antimicrobial taurinamide derivative that are combined with a biologically acceptable acid or biologically accepted salt thereof so as to produce a pH for the ultimate composition that is no higher than 7, preferably in the range of from about 3.5 to about 6.5 more preferably in the range of from about 4.5 to about 6.5 (See Col. 11, Lines 30-40). Various lock solution acid concentrations are mixed 50/50 by weight with fresh whole human blood (See Col 15, Lines 26-30).

### Allowable Subject Matter

7. Claims 3-5, and 7-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Application/Control Number: 09/763,666

Art Unit: 3743

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabrina Dagostino whose telephone number is 703-306-3485. The examiner can normally be reached on M-F 7-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

Sabrina Dagostino

Page 4

Examiner

Art Unit 3743

May 28, 2003

Herry Bennett Supervisory Patent Exam

Group 3700